aap Implantate AG
***aap* Wire Bone**

Summary of Safety and Effectiveness

Sponsor:	***aap* Implantate AG** Lorenzweg 5 D-12099 Berlin Germany
Company Contact:	Dr. Christian Zietsch Phone:+49-30-750-19 -193 Fax: +49-30-750-19 - 111
Date	October/17/ 2013
Trade Name:	*aap* Wire Bone / K-Wire; Cerclage Wire, Steinmann Pin
Common Name:	Wire Bone / K-Wire; Cerclage Wire, Steinmann Pin
Classification Name and Reference:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener - Class II
Device Product Code and Panel Code:	Orthopedics/87/ JDW: Pin, Fixation, Threaded Orthopedics/87/ HTY: Pin, Fixation Smooth
Predicate device:	Bone Wire from Störk Instrumente GmbH, Germany under the premarket notification K030665 (Mar 25, 2003) and Kirschner / Guide Wires from SMT Schilling Metalltechnik GmbH, Germany under the premarket notification K100736 (Sep 10, 2010)
Device Description:	The aap Wire Bone Portfolio consists of K-Wires, Steinmann Pin and Cerclage Wire. The devices have to be used as implants for the fixation of bone fractures, fusion of joints or bone reconstructions or as guide pins for insertion of other implants and are offered in a variety of lengths, diameters, tip styles, and threading. The devices are made of either Titanium alloy or implant stainless steel. The devices are delivered non-sterile and have to be sterilized before use. After fracture healing the implants have to be removed. The aap Wire Bone Portfolio consists of: • K-wire with trocar point, ø0.8 mm - ø3.0 mm, 60 mm – 430 mm • K-wire with thread and trocar point, ø0.8 mm - ø3.0 mm; 45 mm – 380 mm • K-wire with 2 trocar points, ø0.8 mm – ø3.0 mm; 70 mm – 310 mm • Steinmann pin trocar, 3-flat end ø2.5 mm - ø6.0 mm; 120 mm – 350 mm • Cerclage wire with eye, soft, ø0.8 mm - ø1.2 mm; 280 mm – 600 mm • Cerclage wire soft, coil, ø0.8 mm - ø1.5 mm, 10 m

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Material:	Ti6Al4V (ASTM F136 or ISO 5832-3) or Stainless Steel (ASTM F138 or ISO 5832-1)
Indications:	Wire devices (K-Wire, Cerclage Wires, Steinmann Pins) - guide wire for osteosynthesis implants - accessories for external fixation (Steinmann Pin) - application as implant according to the AO/ASIF principles of fracture management
Substantial Equivalence	The proposed devices are substantially equivalent to the identified predicate device in materials of construction, physical characteristics, and intended use. Documentation to show the substantial equivalence and has been provided with this submission.
Performance Data (Non-Clinical and / or Clinical):	The non-clinical testing to be conducted on the aap Wire Bone will include material and dimensional verification. The aap Wire Bone are equivalent in physical dimensions and materials to the identified predicate devices. Testing, therefore, is not needed to demonstrate that the subject devices are substantially equivalent to the legally marketed predicate devices. <u>Summary of performance data:</u> Documentation with respect to performance data to show the substantial equivalence and safety and effectiveness has been provided with this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

aap Implantate AG
Dr. Christian Zietsch
Manager, Regulatory Affairs
Lorenzweg 5
12099 Berlin
GERMANY

Re: K131459
Trade/Device Name: aap Wire Bone
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JDW, HTY
Dated: July 17, 2013
Received: July 19, 2013

Dear Dr. Zietsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Casey Hanley -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131459

Device Name: aap Wire Bone

Indications for Use:

Wire devices (K-Wire, Cerclage Wires, Steinmann Pins)

- guide wire for osteosynthesis implants
- accessories for external fixation (Steinmann Pin)
- application as implant according to the AO/ASIF principles of fracture management

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices